



**National Marrow
Donor Program®**

Entrusted to operate the
C.W. Bill Young
Cell Transplantation Program

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May 11, 2009

Cdr. Elizabeth Montcalm-Smith
Office of Naval Research (ONR 342)
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: Quarterly Performance/Technical Report of the National Marrow Donor Program®

Reference: Grant Award #N00014-06-1-1207 between the Office of Naval Research and the National Marrow Donor Program

Dear Cdr. Montcalm-Smith:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of January 1, 2009 to March 31, 2009.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention (612-362-3403 or at cabler@nmdp.org).

Sincerely,

A handwritten signature in purple ink that reads "Carla Abler-Erickson".

Carla Abler-Erickson, MA
Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

- C: D. Ivery – ACO (ONR-Chicago), letter and enclosure
- Dr. Robert J. Hartzman, CAPT, MC, USN (Ret): letter and enclosure
- Jennifer Ng, PhD – C.W. Bill Young Marrow Donor Recruitment and Research Program, letter and enclosure
- J. Rike - DTIC (Ste 0944): letter and enclosure
- NRL (Code 5227): letter and enclosure
- Dennis Confer, MD, Chief Medical Officer, NMDP, letter only
- Michelle Setterholm, NMDP letter only

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14. ABSTRACT <u>1. Contingency Preparedness:</u> Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan. <u>2. Rapid Identification of Matched Donors :</u> Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event. <u>3. Immunogenetic Studies:</u> Increase understanding of the immunologic factors important in HSC transplantation. <u>4. Clinical Research in Transplantation:</u> Create a platform that facilitates multicenter collaboration and data management.					
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Grant Award N00014-08-1-1207

QUARTERLY
PERFORMANCE / TECHNICAL REPORT
FOR
JANUARY 01, 2009 to MARCH 31, 2009

Office of Naval Research

And

The National Marrow Donor Program
3001 Broadway Street N.E.
Minneapolis, MN 55413
1-800-526-7809

QUARTER PROGRESS REPORT**Development of Medical Technology for Contingency Response to Marrow Toxic Agents****January 01, 2009 through March 31, 2009**

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QUARTER PROGRESS REPORT**Development of Medical Technology for Contingency Response to Marrow Toxic Agents****January 01, 2009 through March 31, 2009****IIA. Contingency Preparedness – Objective 1:** Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians**IIA.1.1 Task 1:**
Secure Interest of
Transplant
Physicians**Period 2 Activity:**

- 26 RITN center staff members attended Advanced Radiation Medical Emergency training course and conducted in Oakridge, TN at the Radiation Emergency Assistance Center/Training Site (REAC/TS) on March 26 & 27, 2009. Course lessons included:
 - Basic Health Physics & Radiation Protection: Part I
 - A History of Serious Radiological Incidents: The Real Risk
 - Health Physics & Contamination Control: Part II
 - Radiation Detection, Monitoring & Protection Laboratory Exercise & Quiz
 - Diagnosis & Management of the Acute Radiation Syndrome (ARS)
 - Diagnosis & Management of Internal Contamination
 - Diagnosis & Management of Acute Local Radiation Injury & Case Review: Yanango Peru
 - Radiation Sources & Radiological Terrorism
 - Radiation Emergency Area Protocol Demonstration
 - Radiation Emergency Medical Management Drill
 - Radiation Dose Estimations – Problem Solving Session
- During this period we continued to plan for the 2009 RITN conference “Nuclear Terrorism: Hematology/Oncology Center Preparedness” to be held in Bethesda, MD on May 18th (additional details of this conference are listed under AIM II A 2.1).

IIA.1.2 Task 2:
GCSF in Radiation
Exposure**Period 2 Activity:**

- No activity this period.

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IIA.1 3 Task 3: Patient Assessment Guidelines and System Enhancements	<p>Period 2 Activity:</p> <p>In the last quarter, a new version of STAR Link was released to support the Navy Contingency project.</p> <ul style="list-style-type: none"> • Sample Tracking – Repository sample storage information is now sent to STAR Link Web. This information will be used to track receipt of returned donor recruitment sample kits. In addition, services have been deployed to send reminder emails back to the donors when they have not returned their kits. This functionality can be extended for contingency donors who have been requested to supply addition samples. <p>Do It Yourself (DIY) application efforts were focused on project enhancements and preparation for the Navy Contingency project including:</p> <ul style="list-style-type: none"> • Kit Requests – System automatically sends sample kit requests after DIY donors register on-line. • Health History Questionnaire (HHQ) - Functionality to allow donors to enter on-line HHQ forms has been developed and is currently being tested. • Statistic: DIY Online Donor Registration through www.marrow.org resulted in a total of 22,011 between 1/1/09 – 3/31/09. • Completed the following project initiation and analysis deliverables to support future releases on the Navy Contingency Project: <ul style="list-style-type: none"> ○ Project scope/charter document ○ Project Quality Assurance Plan ○ Iteration 1 requirements/use case ○ Iteration 2 requirements/use case ○ Draft requirements/use case for iteration 3 (Voids) ○ Began documenting requirements/use case for iteration 4
IIA 1.4 Task 4: National Data Collection Model	<p>Period 2 Activity:</p> <ul style="list-style-type: none"> • No activity this period.

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IIA. Contingency Preparedness – Objective 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.

IIA.2.1 Task 1:
Contingency
Response Network

Period 2 Activity:

- Completed the development of the 2009 RITN Tabletop Exercise and distributed it to all RITN centers to complete prior to the end of July 2009.
- During this period we continued to plan for the 2009 RITN conference “Nuclear Terrorism: Hematology/Oncology Center Preparedness” to be held in Bethesda, MD on May 18, 2009.
 - Based on current registrations we will have approximately 100 attendees
 - During this period we secured as a key note opening address RADM W. Craig Vanderwagen (Assistant Secretary for Preparedness and Response)
 - This conference will have a group session in the morning to provide a common operating picture then have three (3) interactive breakout workshops held three (3) times in the afternoon so that all attendees have the opportunity to participate.
 - Morning sessions include:
 - Threat Scenario Overview
 - National Disaster Medical System
 - Medical response expectations 10, 100, 1,000 miles from epicenter
 - Altered Standards of Medical Care Overview
 - NMDP Planning and data collection
 - Afternoon interactive breakout workgroups include:
 - Altered Standards of Care
 - Logistical issues – bed mgmt, use of non-hospital loc, & staffing issues
 - Provision of medical care – early and late care

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- The conference will culminate with a report of findings by the afternoon session moderators, with the intent of publishing these findings later in the year.
- **Meetings:**
 - 26 Committee members attended the RITN Steering Committee meeting at the 2009 ASBMT/CIBMTR Tandem meetings on February 11, 2009, the meeting agenda consisted of:
 - RITN accomplishments in 2008
 - 2009 expansion of RITN
 - 2009 RITN tasks and educational activities
 - New developments
 - RITN Tabletop Exercises Lessons Learned from 2006-2008 and a 2009 Tabletop Exercise Overview
 - Maintaining RITN's Momentum
 - Continued to plan for a RITN Steering Committee meeting to be held on May 19, 2009 following the RITN educational conference, tentative meeting agenda includes:
 - 2009 conference review
 - 2010 or 2011 conference planning
 - Update on tabletop Lessons Learned project
 - Coordination with HHS on triage of incident victims
 - Update on RITN-VA mapping project
 - Update on JCHO interaction
 - BARDA Presentation
 - Tour of HHS Secretaries Emergency Operations Center

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IIA.2.2 Task 2: Sibling Typing Standard Operating Procedures	Period 2 Activity: <ul style="list-style-type: none"> • No activity this period.
IIA. Contingency Preparedness – Objective 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.	
IIA.3.1 Task 1: I.S. Disaster Recovery	Period 2 Activity: <ul style="list-style-type: none"> • Additional hardware and software was purchased, installed and configured to support disaster recovery testing. Additional network segments were also added to support disaster recovery environment all for completing the upcoming test. • Completed the disaster recovery smoke test for all Tier 1 applications in preparation for the disaster recovery exercise in April 2009. Also, preparations have begun for disaster recovery testing for Tier 2 through 5 applications which will be completed early summer, 2009.
IIA.3.2 Task 2: Critical Facility and Staff Related Functions	Period 2 Activity: <ul style="list-style-type: none"> • Business Continuity Planning: <ul style="list-style-type: none"> ○ Re-evaluated the necessity of and cancelled the installation of high tinsel strength security film on all windows of the NMDP Repository to harden the face of the storage facility in the event of a natural or man made disaster that could compromise the building structure. ○ Began assembling NMDP operated donor center readiness kits to prepare these remote NMDP offices to better respond to incidents that impact their operations.

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IIB. Rapid Identification of Matched Donors – Objective 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.

IIB.1.1 Task 1: Increase Registry Diversity	Period 2 Activity: <ul style="list-style-type: none"> <u>Adult Donor Registry:</u> To successfully serve all patients in need of cellular transplantation, the Marketing and Communications Department continues to focus on developing and executing strategies and tactics that increase awareness, education and engagement among target audiences. During January – March 2009, we focused on transitioning the first phase of our core English and non-English language educational materials to the new public-facing Be The Match (SM) brand name. Be The Match will help educate the general public about the need for unrelated marrow donors and motivate them to join the registry.
IIB.1.2 Task 2: Evaluate HLA-DRB1 High Res typing	Period 2 Activity: <ul style="list-style-type: none"> This activity is closed.
IIB.1.3 Task 3: Evaluate HLA-C Typing of Donors	Period 2 Activity: <ul style="list-style-type: none"> This activity is closed.
IIB.1.4 Task 4: Evaluate Buccal Swabs	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.
IIB 1.5 Task 5: Enhancing HLA Data for Selected Donors	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.
IIB 1.6 Task 6: Maintain a Quality Control Program	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.

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IIB. Rapid Identification of Matched Donors – Objective 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.

IIB 2.1 Task 1: Collection of Primary Data	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.
IIB 2.2 Task 2: Validation of Logic of Primary Data	Period 2 Activity: <ul style="list-style-type: none"> This activity is closed.
IIB 2.3 Task 3: Reinterpretation of Primary Data	Period 2 Activity: <ul style="list-style-type: none"> This activity is closed.
IIB 2.4 Task 4: Genotype Lists & Matching Algorithm	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.

IIB. Rapid Identification of Matched Donors – Objective 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.

IIB.3.1 Task 1: Phase I of EM Haplotype Logic	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.
IIB 3.2 Task 2: Enhancement of EM Algorithm	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.
IIB 3.3 Task 3: Optimal Registry Size Analysis	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.

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IIB 3.4 Task 4: Target Under- Represented Phenotypes	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.
IIB 3.5 Task 5: Bioinformatics Web Site	Period 2 Activity: <ul style="list-style-type: none"> This activity is closed.
IIB 3.6 Task 6: Consultants to Improve Algorithm	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.
IIB 3.7 Task 7: Population Genetics	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.
IIB 3.8 Task 8: Haplotype Matching	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.
IIB 3.9 Task 9: Global Haplotype/Benchmark	Period 2 Activity: <ul style="list-style-type: none"> No activity this period.
IIB. Rapid Identification of Matched Donors – Objective 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.	
IIB.4.1 Task 1: Expand Network Communications	Period 2 Activity: <p>In the last quarter, the effort for has been focused on the analysis and realization of request/fulfillment messaging and storage. This foundation (data model & integration) is a prerequisite for implementing improved electronic communication and parallel search stages.</p> <ul style="list-style-type: none"> Analysis, vetting of request/fulfillment messaging structure through (peer-to-peer) P2P message realization. Analysis, vetting of request/fulfillment storage model.

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Do It Yourself (DIY) application project work efforts delivered the following functionality to allow Donor Centers and Recruitment Groups to use DIY as a recruitment tool:

- Automation of Drive request by DC/RG's – formerly, Recruiters filled out a drive request in SLW, and then faxed in the request. CSS would manually approve these drives.
- Ability to create single use promotional codes and create estimates for a drive.
- Ability to set up multiple funding sources in a single drive. Example: CMF donor paid in which donor pays \$25.00, or CMF sponsor paid, in which a sponsor is billed and the donor responsibility is \$0.
- Prioritization and automation of funding sources which allows recruiters to choose which funding type should be charged first.
- Added CSS functionality, including Stage Drive, Cancel Drive, Estimates Status and Date, View of actual against estimates via the Drive Estimates Grid.
- Setting Drive types: This allowed for automation of “Live” drives as well.
- Drive estimates automatically updating in FDR.
- Automated Status of donors including staged, newly entered, or duplicate.
- Create unique “single use codes” - ability to have SLW automatically generate X number of unique codes for a single drive, with the added functionality to export these promotional codes to a spreadsheet for mail merge.
- Drive max for Caucasian and overall drive totals.
- Automatic invoicing of newly entered donors.
- Automation of emails for kit returned, no kit received, and pending deletion due to incomplete registration in 45 and 60 days.
- UI Interface changes for Pending Donor and Pending Drive including new functionality of screens for additional edits.

DIY 2 - Updated Functionality and User Interface

- Automation of triggers to send emails to donor, email sent after 5, 10, and 15 days.
- Interface changes such as “Verisign” logo.

Reports that will allow tracking of donor recruitment and the supporting activities:

- Drive Activity Reports
- CSS Activity Reports

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	<ul style="list-style-type: none"> • Drive Detail Report <p>FDR</p> <ul style="list-style-type: none"> • FDR will get new pushes of data from STAR Link via transactions. This new interaction will eliminate the need to send a Drive Detail report via email to the FDR user and will replace the “keying” of drive estimates. • Changing the invoicing frequency due to length of drive. Drives longer than 12 days will invoice only monthly compared to the standard weekly.
IIB.4.2 Task 2: Central Contingency Management	<p>Period 2 Activity:</p> <p>A research project was developed to validate the 8/8 HLA high resolution match rate predictions for both Caucasian (CAU) and African American (AFA) patients. This study will validate previous registry benchmark analyses and supply valuable information regarding donor selection in the event of a contingency. During the past quarter:</p> <ul style="list-style-type: none"> • The study design was finalized and work began on the project. • Study ‘patients’ were selected from the random pool of CAU and AFA donors previously high resolution HLA typed through ONR funded haplotype project and the genotypes used to run donor searches against the NMDP registry. • Scientific Services search strategy staff started to perform donor selections on behalf of the study ‘patients’. Beginning next quarter, donors with repository samples will be tested to identify the high resolution match rate for patients.
IIB.4.3 Task 2: Benchmarking Analysis	<p>Period 2 Activity:</p> <ul style="list-style-type: none"> • No activity this period.
IIB.4.4 Task 2: Expand Capabilities of Collection and Apheresis Centers	<p>Period 2 Activity:</p> <ul style="list-style-type: none"> • No activity this period.

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IIC. Immunogenetic Studies – Objective 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.

IIC.1.1 Task 1:
Donor Recipient Pair
Project

Period 2 Activity:

- No activity this period.

IIC. Immunogenetic Studies – Objective 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.

IIC 2.1 Task 1:
Analysis of non-
HLA loci

Period 2 Activity:

- No activity this period.

IIC 2.2 Task 2:
Related Pairs
Research Repository

Period 2 Activity:

- No activity this period.

IIC 2.3 Task 3:
CIBMTR Integration

Period 2 Activity:

- No activity this period.

IID. Clinical Research in Transplantation – Objective 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.

IID.1.1 Task 1:
Observational
Research, Clinical
Trials and NIH
Transplant Center

Period 2 Activity:

- No activity this period.

IID.1.2 Task 2:
Research with
NMDP Donors

Period 2 Activity:

- No activity this period.

IID.1.3 Task 3:
Expand Immuno-
biology Research

Period 2 Activity:

- No activity this period.

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AABB	American Association of Blood Banks	ICRHER	International Consortium for Research on Health Effects of Radiation
AGNIS	A Growable Network Information System	IS	Information Services
AML	Acute Myelogenous Leukemia	IT	Information Technology
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IRB	Institutional Review Board
ASBMT	American Society for Blood and Marrow Transplantation	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
ASHI	American Society for Histocompatibility and Immunogenetics	KIR	Killer Immunoglobulin-like Receptor
B-LCLs	B-Lymphoblastoid Cell Lines	NCI	National Cancer Institute
BARDA	Biomedical Advanced Research and Development Authority	MHC	Major Histocompatibility Complex
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	MICA	MHC Class I-Like Molecule, Chain A
BRT	Basic Radiation Training	MICB	MHC Class I-Like Molecule, Chain B
C&A	Certification and Accreditation	MDACC	MD Anderson Cancer Center
CBMTG	Canadian Blood and Marrow Transplant Group	MSKCC	Memorial Sloan-Kettering Cancer Center
CBB	Cord Blood Bank	MUD	Matched Unrelated Donor
CBC	Congressional Black Caucus	NEMO	
CBS	Canadian Blood Service	NCBM	National Conference of Black Mayors
CBU	Cord Blood Unit	NHLBI	National Heart Lung and Blood Institute
CHTC	Certified Hematopoietic Transplant Coordinator	NIH	National Institutes of Health
CIBMTR	Center for International Blood & Marrow Transplant Research	NIMS	National Incident Management System
CLIA	Clinical Laboratory Improvement Amendment	NK	Natural Killer
CME	Continuing Medical Education	NMDP	National Marrow Donor Program
CMF	Community Matching Funds	NRP	National Response Plan
COG	Children's Oncology Group	NST	Non-myeloablative Allogeneic Stem Cell Transplantation

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CREG	Cross Reactive Groups	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CSS	Center Support Services	OIT	Office of Information Technology
CT	Confirmatory Testing	OMB	Office of Management and Budget
CTA	Clinical Trial Application	ONR	Office of Naval Research
DC	Donor Center	P2P	Peer-to-Peer
DIY	Do it yourself	PBMC	Peripheral Blood Mononuclear Cells
DKMS	Deutsche Knochenmarkspenderdatei	PBSC	Peripheral Blood Stem Cell
DMSO	Dimethylsulphoxide	PCR	Polymerase Chain Reaction
DNA	Deoxyribonucleic Acid	PSA	Public Service Announcement
D/R	Donor/Recipient	QC	Quality control
EBMT	European Group for Blood and Marrow Transplantation	RCC	Renal Cell Carcinoma
EM	Expectation Maximization	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
EMDIS	European Marrow Donor Information System	REAC/TS	Radiation Emergency Assistance Center/Training Site
ERSI	Environment Remote Sensing Institute	RFP	Request for Proposal
FBI	Federal Bureau of Investigation	RFQ	Request for Quotation
FDA	Food and Drug Administration	RG	Recruitment Group
FDR	Fund Drive Request	RITN	Radiation Injury Treatment Network
Fst	Fixation Index	SBT	Sequence Based Typing
GETS	Government Emergency Telecommunications Service	SCTOD	Stem Cell Therapeutics Outcome Database
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	SG	Sample Group
GIS	Geographic Information System	SLW	STAR Link® Web
GvHD	Graft vs Host Disease	SSA	Search Strategy Advice
HCT	Hematopoietic Cell Transplantation	SSO	Sequence Specific Oligonucleotides
HHS	Health and Human Services	SSP	Sequence Specific Primers
HIPAA	Health Insurance Portability and Accountability Act	SSOP	Sequence Specific Oligonucleotide Probes

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HLA	Human Leukocyte Antigen	STAR®	Search, Tracking and Registry
HML	Histoimmunogenetics Mark-up Language	TC	Transplant Center
HR	High Resolution	TED	Transplant Essential Data
HRSA	Health Resources and Services Administration	TNC	Total Nucleated Cell
HSC	Hematopoietic Stem Cell	TSA	Transportation Security Agency
IBWC	Immunobiology Working Committee	UI	User Interface
IDM	Infectious Disease Markers	URD	Unrelated Donor
IHWG	International Histocompatibility Working Group	WGA	Whole Genome Amplification
IPR	Immunobiology Project Results	WMDA	World Marrow Donor Association
IND	Investigational New Drug	WU	Work-up